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Application No. / Patent No. 94 910 858.3-2310 / 0688189 /	Ref. 012886ep/TW	Date 17.02.2003
Proprietor WAKE FOREST UNIVERSITY		

Interlocutory decision in Opposition proceedings (Articles 102(3) and 106(3) EPC)

The Opposition Division - at the oral proceedings dated 12.12.2002 - has decided:

Account being taken of the amendments made by the patent proprietor during the opposition proceedings, the patent and the invention to which it relates are found to meet the requirements of the Convention.

The reasons for the decision are enclosed.

Documents for the maintenance of the patent as amended:

Text for the Contracting States:
AT BE CH LI DE DK ES FR GB GR IE IT LU MC NL PT SE

Description, pages:

2-15 of the patent specification

Claims, No.:

2-34 during oral proceeding on 12.12.2002

1 introduced by the division

Drawings, No.:

1-11 of the patent specification

**With the following amendments to the above-mentioned documents according to your request
dated 12.12.2002:**

Description, pages: 3",4"

**Comments:**

- ** Rule 27(1, b) EPC
- *** the Guidelines C-III, 4.3iii)
- * retyped for legibility; two-part form in accordance with Patentee [Rule 29(1) EPC]

Possibility of appeal

This decision is open to appeal. Attention is drawn to the attached text of Articles 106 to 108 EPC.

Opposition Division:

Chairman: GEORGIOU Z
2nd Examiner: ARJONA LOPEZ G
1st Examiner: MERTE B E A



Neresheimer, E
Formalities Officer
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12.02.03 NH

Enclosure(s): 7 page(s) reasons for the decision (Form 2916)
Wording of Articles 106 - 108 (Form 2019)
Documents relating to the amended text
[] Minutes of oral proceedings
ANNEXes 1-3

to EPO postal service: 12.02.2003

Europäisches Patentamt
DG2 - Einspruch

European Patent Office
DG2 - Opposition

Office européen des brevets
DG2 - Opposition

Application No.:

94 910 858.3

Patent No.:

EP-B-0688189

**A copy of the communication (communication/decision/minutes) was printed for and
notified to each of the following representatives/parties:**

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Entscheidungsgründe (Anlage)	Grounds for the decision (Annex)	Motifs de la décision (Annexe)
Datum Date Date **CODINGDATE**	Blatt Sheet Feuille 1	Anmelde-Nr.: Application No.: 94 910 858.3 Demande n°:

1. Facts and Submissions

1.1 European Patent No. **0688189** is based upon European patent application No. **94910858.3**

Date of filing: **17/03/94**

Claimed priority: **09/03793 (US28677)**

Date of publication and mention of the grant of the patent:

13/09/00 - Bulletin 2000/37

Proprietor: **WAKE FOREST UNIVERSITY**
Winston-Salem, NC 27157-1023 (US)

Notice of Opposition has been filed on **12/06/01** with letter of **12/06/01** by the

Opponent: **Mondomed N.V.**
Middenweg 12, B - 3930 Hamoni-Achel (BE)

1.2 A copy of the text of the independent **claim 1** as amended during the Oral Proceedings of **12/12/02** on which the decision is based is annexed (see **ANNEX 1**).

1.3 A list of documents submitted in evidence by the **Opponent** with the letter of opposition dated **12/06/01** is to be found on **ANNEX 2**. Among those documents, the following ones are particularly relevant for the decision:

D1=: US-A-4969980

D5=: US-A-2280915 and

WO93/09727 (named **D9** during the OP of **12/12/02** and part of the prior art under Article 54(3) EPC)

2. Requests

2.1 The **Opponent** requests revocation [Article 102(1) EPC] of the patent as a whole for lack of patentability under Articles 54 and 56 EPC [Articles 99 and 100(a) EPC].



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2.2 Conversely, in his reply dated 25/01/02 to the letter of opposition the **Patentee** requests maintenance of the patent as granted, and auxiliarily Oral Proceedings. With letter dated 11/11/02 he auxiliarily requests maintenance of the patent on the basis of one of the then filed **AUXILIARY REQUESTS 1-3**.

2.3 On 10/07/02 the **Opposition Division** issues a **communication** appended to the summons for the OP requested by both parties as auxiliary measure. In this communication a preliminary statement is given saying that the **Opposition Division** considers the subject-matter of **Claim 1** as granted to be new over document D5 as the closest state of the art.

2.4 With letter of 12/11/02 the **Opponent** gives additional arguments, primarily concerning novelty or inventive step with respect to document D5 or document D5 in combination with general knowledge or document D1, respectively. Furthermore, he objects to the **AUXILIARY REQUESTS 1 and 3** for lack of compliance with **Article 123(3) EPC**.

2.5 During the OP of 12/12/02 finally an amended set of **claims 1-34** is filed, **claim 1** as granted being supplemented by the subject-matter of **claims 15 and 19** as granted and the replacement "cover is sheet-like" by "cover is a flexible sheet". The **Patentee** withdraws all his former requests to replace them by the **request to maintain the patent as amended** during the OP of 12/12/02 [**Article 102(3) EPC**]. The **Opponent** withdraws his **request for revocation** of the patent on grounds of lack of **novelty** with respect to document D9 and to document D5 [**Article 100(a)** in combination with **Article 54(1, 2) or (1, 3) EPC**] as well as **unallowable extension of the scope for the claims** [**Article 100(c)** in combination with **Article 123(3) EPC**] that had been brought forward during the written procedure with respect to meanwhile obsolete - however analogous - auxiliary requests (see **point 2.4**).



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3. Decision

- 3.1 The opposition is admissible because it meets all requirements of Article 99(1) and 100 EPC and of Rules 1(1) and 55 EPC.
- 3.2 After being asked for during the OP, the Representative of the Patentee confirms that the embodiments shown in Figures 1-3 and 10-11 of the opposed patent do not depict all the features of the claimed invention, ie they do not fall under the scope of the claims.

3.3 Document D9=: WO93/09727A

In the letter of opposition dated 12/06/01 document D9 is introduced, however without providing concrete details attacking the claims as granted.

During the OP of 12/12/02 the following features of claim 1 are identified as being anticipated by document D9:

- appliance for reduced-pressure treatment (D9: p. 6, I. 7)
- (a) impermeable cover (D9: p. 8, I. 20; p. 9, I. 14; IOBAN is impermeable p. 9, I. 41)
In particular, this IOBAN sheet (D9: EX 6) is suitable to perform all three functions enumerated in claim 1, ie covering and enclosing the wound and maintaining reduced pressure (D9: p. 8, I. 20ff, I. 32)
- (b) seal operably connected to cover (D9: p. 8 I. 20; p. 9, I. 26-27)
- (c) rigid support means (D9: p. 8, I. 32-33; CPR mask: EX of Fig.2)
- (d) reduced pressure supply means (D9: p. 8, EX 1; p. 10, I. 21), which is operately connected in its broadest sense to the cover (D9: Fig. 1)
- (e) the IOBAN tent forming the cover is sheet-like (D9: p. 8, I. 22)

and

- (f) is associated with and separate from the cover (D9: EX 6).

In addition to those features constituting claim 1 as granted, claim 1 as amended during the OP of 12/12/02 further comprises the features that

- the cover is a sheet [A]
- the reduced pressure supply means comprises a vacuum source for producing a reduced pressure [B]

and



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- the reduced pressure supply means comprises a length of tubing connected between said vacuum system and said cover [C] , and
 - a vacuum pump connected with said tubing [D] and
 - a filter for preventing said pump from venting micro-organisms from the wound [E].

Against the thus amended **claim 1** the Opponent does not object under **Article 54 EPC** nor under **Article 123(2) or (3) EPC**.

In particular, the feature that the cover is a sheet is apparent from Figs. 4-6 (see also p. 8, l. 4-5, l. 24-25, l. 42). It implies a limitation rather than an extension to the scope of **claim 1**. Furthermore, the subject-matter of **claims 16 and 20** as granted is integrated in the subject-matter of this amended **claim 1**. Therefore, the opposition division acknowledges compliance with **Article 123(2) and (3)**.

The above mentioned features introduced to **claim 1** during the OP of 12/12/02 are not disclosed in document **D9** and - therefore - suitable to establish novelty in the sense of **Article 54(1, 3) EPC**. Since document **D9** is part of the prior art under **Article 54(3) EPC** only, inventive step [**Article 56 EPC**] can not be under dispute.

3.4 Document D5=: US-A-2280915

3.4.1 Novelty [**Article 54(1, 2) EPC**]

As the appliance for administering a reduced pressure treatment to a wound of document **D5** (**D5: p. 1, l. col., l. 12-15**) clearly comprises at least a cover for covering and enclosing the wound (**D5: Fig. 3; p. 1, r.col., l. 12-29**), a seal for sealing said cover to tissue surrounding the wound (**D5: p. 1, r.col., l. 31-34**), rigid support means (**D5: p. 2, l.col., l. 31-48**), and reduced pressure supply means comprising a length of tubing (**D5: p. 2, l.col., l. 54-58**), document **D5** is considered to represent the closest state of the art by both parties. The remaining features, however, are under dispute. In particular:

- [i] the cover is impermeable for maintaining reduced pressure
- [ii] the seal is operably connected with the cover
- [iii] the cover is a sheet
- [iv] the reduced pressure supply means comprises a vacuum pump
- [v] the reduced pressure supply means comprises a filter for preventing said pump from venting micro-organisms aspirated from the wound.



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With respect to feature [i] the **Opponent** brings forward that in document D5 the cover is impermeable, because for applying suction through one of the two openings the other one is closed (D5: Fig. 3; p. 2, l.col., l. 53-48); therefore, the D5 device is suitable for **maintaining** reduced pressure.

Using a copy of **Fig. 2** of document D5 handed out during the **OP** the **Proprietor** explains that this device is intended for **irrigation** of the wound either by sucking the irrigation fluid or by pressing it through the system, but not for maintaining reduced pressure over the wound.

The **opposition division** has to acknowledge that the D5 system actually is **suitable for maintaining reduced pressure** in the sense of the wording of **claim 1** thanks to its configuration comprising an impermeable cover in combination with a **sealing arrangement** (D5: p. 1, r. col., l. 30-34).

Against the **Opponent's** argumentation that a seal which is integral with the cover as that of D5 (D5: p. 1, r.col., l. 30-36; Fig. 3) automatically is operably connected with the cover, the **Patentee** hold that the wording "operably connected" refers to a functional relationship, but does not mean "integral" in the sense that it is "manufactured in one piece". Since there is necessarily a functional relationship between parts which are integral as the seal and the cover in document D5, the wording "operably connected" (feature [ii]) covers the D5 device.

Though the **Opponent** alleges that the cover in document D5 in the form of a **rubber pad** (D5: p. 1, r.col., l. 12-14) expanded to a cup-shaped form by the rigid cup (D5: Fig. 1) is a **sheet**, the opposition division is of the opinion that it is not appropriate to name anything which used to be a **sheet** before being produced still a **sheet**. The terms "sheet" and "rubber pad" in their respective context are clearly distinguishable. Therefore, the cup-shaped flexible cover of D5 can not be regarded as a **sheet**, and feature [iii] is novel over D5.

With respect to feature [iv] the **Opponent** brings forward that the skilled man automatically uses a vacuum pump when he is supposed to use "any suitable suction-producing means" as suggested in D5 (D5: p. 2, l.col., l. 54-56). In spite of the **Patentee's** comment that nowhere in D5 a vacuum is explicitly identified the opposition division has to confirm that "any suitable suction-producing means" for the skilled reader is nothing but a vacuum pump, and feature [iv] is implicitly disclosed in document D5. No technical difference can be attributed in the context of the present patents to the terms "vacuum pump" and "suction pump".



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Having regard to feature [v] the **Opponent** mentions that normal vacuum pumps actually do comprise filters. Since in document D5 no explicit mention is made of any filter, and in particular not of a filter in connection with a system falling under the scope of **claim 1**, feature [v] must be considered as being new over the teaching of document D5.

Summarising, the subject-matter of **claim 1** meets the requirement of novelty [**Article 54(1, 2) EPC**], because it differs from document D5 as being representative for the closest state of the art in that

- [1] the cover is a sheet (feature [iii] above)
and in that
- [2] the reduced pressure supply means comprises a filter for preventing said pump from venting micro-organisms aspirated from the wound (feature [iii] above).

3.4.2 Inventive Step [**Article 56 EPC**]

The **Opponent** alleges that the skilled reader would necessarily use a cover in the form of a sheet, since the cover of D5 is already a sheet, at least partially (surrounding pad reference numeral 1 in Fig. 1 of D5). Also, in view of document D1 which is in the same technical field, the skilled reader would recognise that a cover formed by a sheet allows for a much simpler design, thus saving production costs, and providing for much more flexibility concerning conformity to the respective body part and the size of the wound treatment device. The **Proprietor** explained that thanks to the special design of the cover as a sheet, the device of the application provides for faster healing by closing the wound not only by the application of negative pressure to enhance tissue ingrowth but also by bringing the edges of the wound closer together, thus avoiding traumatic stitching. The **objective problem** of the application being **acceleration of healing and improved closure of a wound**, the opposition division considers that the skilled reader, starting from document D5 that teaches to keep the wound open for irrigation, would not be led to modify the D5 design by incorporating the cover-sheet of document D1, document D1 not even being suitable for applying reduced pressure, in order to solve the problem posed.



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Even if the provision of filters (feature [2]) in connection with any suction pumps might be considered as a generally well known technical measure, there is no reason why the skilled person should equip the device of D5 that provides suction for irrigation of a wound, thereby the wound being kept open, with a sheet for covering and with such a filter, the problem of venting micro-organisms from the wound into the atmosphere being non-existent, since a wound irrigated by a disinfectant does not have any micro-organisms.

4. Conclusion

Taking account of the above, and in view of the objective problem of improving healing of a wound in the light of the known prior art, it is considered that the skilled person would not have combined the teaching of document D5 with general knowledge or with the teaching given in document D1 to arrive at the subject-matter of **claim 1** as filed during the OP of 12/12/02. Therefore, the subject-matter of **claim 1** meets all requirements of the EPC. The Opponent was explicitly informed about the amendments to be performed upon request of the **Patentee** by the **opposition division**. No objection has been raised. Thus, the patent is maintained in amended form [**Article 102(3) EPC**].

ANNEX 1

94910858.3
Wake Forest University

11 November 2002

12 December

~~First Auxiliary Request~~

~~Second filed during~~

OP of 12/12/02

Claims

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1. An appliance (29c) for administering a reduced pressure treatment to a wound comprising:

10 (a) an impermeable cover (117) for covering and enclosing the wound (114) and for maintaining reduced pressure at the site of the wound;
(b) a seal (119) operably connected with the cover (117) for sealing said cover to tissue surrounding the wound;
(c) rigid support means (118); and
15 (d) reduced pressure supply means (112) operably connected with the cover for connection to a source of suction for supplying and maintaining said reduced pressure beneath the cover, characterised in that said cover (117) is sheet-like and in that said rigid support means (118) is associated with and separate from said cover (117) for holding the cover out of contact with the wound, and [] and <>.
[] is a flexible sheet (128)

2. An appliance according to claim 1, characterised in that it further comprises a screen (100) for preventing overgrowth of wound tissue, said screen (100) being positioned between said wound (114) and said cover (117).

3. An appliance according to claim 2, characterised in that said screen (100) comprises a porous sheet.

4. An appliance according to claim 1, characterised in that said reduced pressure is from about 6.77 kPa (2 inch Hg) 25 below atmospheric pressure to about 23.70 kPa (7 inch Hg) below atmospheric pressure.

5. An appliance according to any of claims 1 to 4, characterised in that said seal (119) includes an adhesive material on the cover for securing said cover to the tissue surrounding the wound.

30 6. An appliance according to claim 1, characterised in that said cover comprises a flexible sheet (128).

6 7. An appliance according to claim 6, characterised in that the support means (138) connects with said sheet (128) for supporting said sheet outward from the wound.

7 8. An appliance according to claim 7, characterised in that said support means comprises a support member (138) located between said sheet and the wound.

8 9. An appliance according to claim 8, characterised in that said support member includes a porous cup member (138), having a connection port (134) for connecting with said reduced pressure supply means (132).

9 10. An appliance according to claim 9, characterised in that it further comprises a pad (120) between the wound (124) and said support member (138) for alleviating discomfort caused in the wound by said support member.

10 11. An appliance according to claim 10, characterised in that said support means comprises a support member (151) extending outwardly over the wound (144) and external to said sheet (148).

11 12. An appliance according to claim 11, characterised in that said support means comprises attachment means for attaching said sheet to said support means, said attachment means having a connecting member (153) for connecting with said reduced pressure supply means for providing said reduced pressure beneath said sheet, and said support member (151) comprising a plurality of leg members (158) attached to said attachment means for holding said attachment means and said sheet outward from the wound.

12 13. An appliance according to claim 12, characterised in that said screen is adapted for placement at a location between the wound and said cover to prevent overgrowth of the wound and is secured in said location at the periphery of said cover.

13 14. An appliance according to claim 13, characterised in that said screen comprises a sheet-like mesh.

RU

14 18. An appliance according to claim 12, characterised in that said seal includes an adhesive material on the cover for adhering to tissue surrounding the wound and a seal member at least partially overlying said cover.

15 16. An appliance according to any of the preceding claims, characterised in that said reduced pressure supply means comprises a vacuum system for producing a reduced pressure

16 17 15 18. An appliance according to claim 16, characterised in that said vacuum system includes a collection device for collecting fluid aspirated from the wound.

17 16 16 18. An appliance according to claim 17, characterised in that said collection device includes means for halting said application of reduced pressure to the wound when said fluid exceeds a predetermined quantity.

18 17 15 17 18. An appliance according to any of claims 18 to 18, characterised in that said reduced pressure is from about 6.77 kPa (2 inch Hg) below atmospheric pressure to about 23.70 kPa (7 inch Hg) below atmospheric pressure.

19 19 15 19 18. An appliance according to any of claims 18 to 19, characterised in that said reduced pressure supply means comprises a length of tubing connected between said vacuum system and said cover and in that said vacuum system comprises:

20 (a) a vacuum pump connected with said tubing; and
 (b) a filter for preventing said pump from venting micro-organisms aspirated from the wound >>

21 18. An appliance according to claim 20, characterised in that said filter is connected along said tubing between said pump and said cover for preventing contamination of said pump.

22 21 15 20 19. An appliance according to any of claims 18 to 21, characterised in that said vacuum system comprises control means for cyclically controlling said production of reduced pressure in alternating periods of production and non-production of reduced pressure.

23 20 15 21 22. An appliance according to claim 18, characterised in that said reduced pressure supply means comprises a length of tubing and said vacuum system comprises an aspirating container connected along said length of tubing between said vacuum system and cover and a flotation valve within said aspirating container for blocking said tubing when a predetermined amount of fluid is collected within said container.

24 21 15 21 23. An appliance according to claim 18, characterised in that said vacuum system comprises an expandable chamber and sensing means for sensing expansion of said expandable chamber, said sensing means being operatively connected with said vacuum system so that application of a reduced pressure to the wound is halted when a predetermined expansion of said expandable chamber is sensed by said sensing means.

25 22 15 21 24. An appliance according to claim 18, characterised in that said reduced pressure supply means comprises a length of tubing and said halting means comprises a filter along said tubing, said filter having pores that block the supply of reduced pressure via said tubing when said pores are filled with said fluid.

26 23 15 23 25. An appliance according to claim 1, characterised in that said reduced pressure supply means comprises an open cell foam screen for applying the reduced pressure to the wound, and a tube member embedded in said screen for extending from beneath the cover and for supplying the reduced pressure to said foam.

27 24 15 23 26 26. An appliance according to claim 25, characterised in that said tube member has a side port within the foam for promoting substantially uniform application of reduced pressure to the wound.

28 25 15 23 27. An appliance according to claim 26 or 27, characterised in that said foam screen is adapted to be conformed to the shape and size of the wound.

29 26 15 26 28. An appliance according to claim 1, characterised in that:

30 (a) said cover comprises a deformable cover for placement over the wound;
 (b) said seal comprises an adhesive layer on the cover for forming a seal between said cover and tissue surrounding the wound;

1. An appliance (29c) for administering a reduced pressure treatment to a wound comprising:
 - (a) an impermeable cover (117) for covering and enclosing the wound (114) and for maintaining reduced pressure at the site of the wound;
 - (b) a seal (119) operably connected with the cover (117) for sealing said cover to tissue surrounding the wound;
 - (c) rigid support means (118) associated with and separate from said cover for holding the cover out of contact with the wound;
 - (d) reduced pressure supply means (112) operably connected with the cover for connection to a source of suction for supplying and maintaining said reduced pressure beneath the cover, said reduced pressure supply means comprising a vacuum system for producing a reduced pressure, wherein said reduced pressure supply means comprises a length of tubing connected between said vacuum system and said cover, said vacuum system comprising a vacuum pump connected with said tubing;

characterised in that

 said cover (117) is a flexible sheet (128)

and in that

 said vacuum system further comprises a filter for preventing said pump from venting micro-organisms aspirated from the wound.